IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	10/755,038	Confirmation No.:	7887
Applicant	:	Avram Reuben Gold		
Filed	:	January 9, 2004		
Title	:	METHOD OF TREATING FUNCTIONAL SOMATIC SYNDROMES AND DIAGNOSING SLEEP DISORDERS BASED ON FUNCTIONAL SOMATIC SYNDROME SYMPTOMS		
Group Art Unit	:	3771		
Examiner	:	Adam Curtis Brandt		

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Commissioner for Patents
P.O. Box 1450
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DECLARATION UNDER 37 C.F.R. §1.132

Sir:

I, Mark H. Sanders, hereby declare and state as follows:

1. I am a graduate of the State University of New York Upstate Medical Center, earning my Medical Doctorate in 1974. I completed an Internship and a Residency in Medicine at the Emory University Affiliated Hospitals in 1977 and was a Fellow in Pulmonary Medicine at the Emory University Affiliated Hospitals in 1978. From 1978 until 1980, I was a Fellow in Pulmonary and Critical Care Medicine and Pulmonary Research at the University of Oklahoma Health Sciences Center. My specialty certifications include the American Board of Sleep Medicine, the American Board of Internal Medicine, and the Subspecialty of Pulmonary Medicine. In addition, I was formerly certified in Critical Care Medicine.

2. From 1982 until 1995, I was the Medical Director of the Pulmonary Sleep Evaluation Laboratory at the University of Pittsburgh Medical Center. From 1982 until the present, I have been the Director of the Pulmonary Sleep Research and Control of Breathing Laboratory at the University of Pittsburgh. From 1991 until 2002, I was Chief of the Pulmonary

Sleep Disorders Program at the University of Pittsburgh Medical Center and from 2003 until the present, I have been the Director of Research of this program. From 1980 until 1982, I was an Assistant Professor of Medicine and Director of the Medical Intensive Care Unit at the University of Cincinnati College of Medicine. From 1982 until 1989, I was an Assistant Professor of Medicine at the University of Pittsburgh School of Medicine. From 1989 until 1996, I was an Associate Professor of Medicine (primary appointment) and Anesthesiology (secondary appointment) at the University of Pittsburgh School of Medicine. From 1996 until the present, I have been a Professor of Medicine and Anesthesiology at the University of Pittsburgh School of Medicine.

3. I have read the subject Application of which Dr. Avram Gold is the inventor, together with the November 21, 2006 Office Action and the documents cited against the claims of the Application, particularly Pantino (U.S. Patent No. 6,769,910) and Thornton (U.S. Patent No. 5,954,048).

4. I have reviewed the rejections in the November 21, 2006 Office Action ("Office Action") alleging that the Application is enabling, as stated in the Office Action with regard to a "method of treating the particular functional somatic syndrome of fibromyalgia, UARS and OSA/H", but does not reasonably provide enablement for treating other functional somatic syndromes without undue or unreasonable experimentation.

5. I conclude that the Application, when read by one skilled in the art, would allow such person to practice the full scope of the claims without undue or unreasonable experimentation. Dr. Gold's disclosure correctly identifies a definition of functional somatic syndromes (FSS) as being physical syndromes without an organic disease explanation, demonstrable structural changes, or established biochemical abnormalities that comports with the medical literature relating to functional somatic syndromes, (See paragraph [0005] of the Application). He further correctly identifies a medical literature-identified listing of functional somatic syndromes to include: chronic fatigue syndrome, fibromyalgia, irritable bowel syndrome, migraine headaches, tension headaches, temporomandibular joint syndrome, premenstrual syndrome, multiple chemical sensitivity, sick building syndrome, repetition stress injury, side effects of silicone breast implants, Gulf War syndrome, chronic whiplash, and restless leg/periodic limb movement syndrome, (See paragraph [0005] of the Application). Further, one skilled in the medical art, namely, a medical doctor, would be able to diagnose a

patient as suffering from a functional somatic syndrome based on the appearance of one or more of these conditions without a medical explanation. Dr. Gold's Application clearly articulates his thesis statement that inspiratory airflow limitation during sleep has a likely underlying or unifying role in the development of the functional somatic syndromes and can be treated by correcting inspiratory airflow limitation during sleep, (See paragraphs [0009], [0022] and [0057] of the Application). This is accomplished as disclosed in the Application by stabilizing the upper airway of the patient using one or more kinds of upper airway stabilization devices or techniques, (See paragraphs [0025] of the Application). He enumerates clearly in several locations in the Application, (See, for example, paragraphs [0022], [0056], [0066] of the Application) that treatment of inspiratory airflow limitation during sleep may be used to treat the functional somatic syndromes and is not confined to treating any one of the individual functional somatic syndromes, such as fibromyalgia. Exemplary devices/apparatus for use in upper airway stabilization via positive airway pressure therapy are provided in the Application in paragraphs [0026], (CPAP) and [0029], (mechanical stabilization) as examples. Based on the foregoing evidence, one skilled in the art would understand from this Application that the inventor claims that inspiratory airflow limitation during sleep has a likely underlying or unifying role in the development of the functional somatic syndromes and treating or correcting inspiratory airflow limitation during sleep is likely to be effective in addressing this potential root cause of functional somatic syndromes. Moreover, based on the foregoing evidence, one skilled in the art would be able to practice Dr. Gold's teaching because multiple common or well-known upper airway stabilization techniques are described in the Application in connection with the claimed treatment methods. Accordingly, I conclude that the Application teaches that a patient suffering from inspiratory airflow limitation followed by an identification or determination of the presence of a functional somatic syndrome (or one or more symptom thereof) could be treated by the methods and apparatus disclosed in the Application without undue or unreasonable experimentation. It would be understood by one skilled in the art, after reading Dr. Gold's disclosure, that the disclosed methods and apparatus are not intended to be limited to the treatment of fibromyalgia as in Example II but are intended to treat functional somatic syndromes generally once inspiratory airflow limitation during sleep has been identified in a patient. One skilled in the art would not be required to perform undue experimentation based on this disclosure to apply the claimed methods and apparatus to a specific functional somatic

syndrome or syndromes and would recognize that the specific fibromyalgia example, Example II, beginning on page 17 of the Application, is merely a representative example for treating any individual functional somatic syndrome, as this is the intent of Dr. Gold's disclosure. I find that it is quite clear that the methods and apparatus identified in Dr. Gold's disclosure may be used, without undue or unreasonable experimentation, to treat a patient identified as suffering from any of the functional somatic syndromes or symptom(s) thereof once upper airway limitation during sleep has been determined in the patient.

6. I have reviewed the rejections in the Office Action alleging that the claims are obvious over Pantino in view of Thornton. In particular, I have reviewed the position set forth in the Office Action that Pantino discloses a method of treating functional somatic syndromes including the steps of identifying a patient as having a functional somatic syndrome and treating the patient with an upper airway stabilization technique, and that it would have been obvious to include the continuous positive airway pressure ("CPAP") stabilization technique taught by Thornton in the Pantino method to treat the patient. I have also reviewed the position set forth in the "Response to Arguments" outlined in the Office Action, which alleges that the combination of Pantino's mechanical oral appliance modified with Thornton's CPAP device is capable of treating the functional somatic syndromes and therefore renders the claimed methods obvious and unpatentable.

7. Based on my reading of the Pantino disclosure, this patent is limited to an orally-inserted device for improving breathing, and abating or completely alleviating snoring sounds, temporomandibular joint syndrome ("TMJ"), and bruxism while sleeping. It is well-known that such oral devices or appliances often have a benefit of treating the physical symptoms associated with TMJ and bruxism due to the fact that the oral appliance repositions the lower jaw, separates the upper and lower jaw, and fixes the lower jaw relative to the upper jaw while sleeping. It is my belief that one skilled in the art would understand that the Pantino disclosure and the oral appliance therein is directed primarily to treatment of sleep disordered breathing by the physical repositioning of the lower jaw and that the additional benefit of this repositioning is the reduction of the symptoms of TMJ and bruxism in the patient by "minimizing the negative effects of a static positioning of the: 1) teeth and related muscles and ligaments", (See Pantino column 4, lines 63-64). Accordingly, there is nothing in the Pantino disclosure relating to a causal connection or linkage between inspiratory airflow limitation

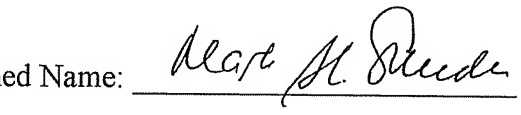
during sleep as a likely underlying or unifying cause of the functional somatic syndromes as per Dr. Gold's disclosure and, thus, no recognition on the part of Pantino that his mechanical oral device would in any way be applicable to or capable of treating the functional somatic syndromes. The fact that the Pantino oral appliance can additionally treat the symptoms of TMJ and bruxism in no way leads one skilled in the art to conclude that it can be used to treat functional somatic syndromes generally. Thus, the claimed treatment methods are not taught or suggested. It is further clear to me that the Pantino device is a mechanical device and one skilled in the art would not be motivated in any way to add a positive airway pressure component to this mechanical device for treatment of TMJ and bruxism as the mechanical oral device itself provides the benefit of treating the symptoms associated with TMJ and bruxism by repositioning the lower jaw (e.g., mandible). Based on the teachings of Pantino (limited to a mechanical oral appliance), the addition of a positive airway pressure therapy component would add nothing to the treatment of TMJ and bruxism and would be unnecessary. Finally, I respectfully disagree with the general contention in the Office Action that it would be obvious to one skilled in the art to add a positive airway pressure component to the Pantino oral appliance for the treatment of the functional somatic syndromes. Only Dr. Gold's Application identifies a causal connection between inspiratory airflow limitation during sleep and the functional somatic syndromes and further teaches the corrective regimen of upper airway stabilization, whether by mechanical means and/or positive airway pressure therapy means. Pantino and Thornton do not even hint to such a connection.

8. The device disclosed in Thornton is intended to treat sleep disordered breathing such as snoring and sleep apnea using positive airway pressure therapy. The device is not intended to or disclosed in any way as being suitable for treating functional somatic syndromes. Until Dr. Gold's recent disclosure, the use of a CPAP device to treat functional somatic syndromes was unknown and, consequently, untried and such a device would not have been used by one skilled in the art to treat a functional somatic syndrome. It would be non-obvious to do so. As with Pantino, Thornton does not disclose or suggest a possible relationship between inspiratory airflow limitation during sleep and the functional somatic syndromes and, thus, provides no motivation for the use of positive airway pressure therapy in the treatment of functional somatic syndromes. As indicated previously, I find no reason to conclude that one having skill in the art would have been motivated to combine the CPAP system of Thornton with

the mechanical treatment of sleep disordered breathing in Pantino to treat a patient suffering from a functional somatic syndrome. It is only Dr. Gold's disclosure that identifies a causal connection between an inspiratory airflow limitation during sleep and the functional somatic syndromes and identifies a corrective remedy in the form of upper airway stabilization.

9. In summary, Pantino and Thornton provide no teaching or suggestion relating to a possible clinical connection between an inspiratory airflow limitation during sleep and the functional somatic syndromes as does Dr. Gold's Application. Accordingly, these patents do not in any way teach or suggest the suitability or desirability of either mandibular stabilization or continuous positive airway pressure therapy (or a combination thereof) in the treatment of functional somatic syndromes once inspiratory airflow limitation during sleep has been identified in a patient. One skilled in the art would not have recognized from either of these disclosures that upper airway stabilization may be valuable in treating the functional somatic syndromes once inspiratory airflow limitation during sleep has been determined without first consulting Dr. Gold's Application. Further, one having skill in the art with knowledge of Pantino and Thornton would not have been motivated to combine the CPAP device in Thornton with the mechanical treatment of sleep disordered breathing in Pantino to treat a patient identified as suffering from a functional somatic syndrome or symptom thereof for the reasons detailed previously in Paragraph 7 above.

10. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the Application or any patent issuing thereon.

Signed Name: 

Typed Name: Mark H. Sanders, M.D.

Date: May 16, 2007